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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/621,565

07/21/2000

Miri Seiberg

JBP0510

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04/19/2006

Audley A Ciamporcero Jr Esq
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/621,565	SEIBERG ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 68-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 68-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 1/27/2006. Claims 1-22 and 68-70 are pending.

1. MATTERS ADDRESSED ON 2/08/02 is excluded in current claims.

Claim 2 was amended in the amendment filed 2/08/02, same amended claim was filed with the appeal brief filed 5/20/02. Previously amended claim cannot be resubmitted as original claims. Specifically, claim 1 does not support the recitation of "extract" in claim 2. Claim 2 was amended on 2/08/02 in which the term "extract" was replaced with ---compound---, which has support, in the claims 1 as originally filed.

The reintroduction of the original claim containing the extract occurred with the amendment filed 2/17/2004. This reintroduction of amended claim as original claim was not noticed and the issue was not addressed at that time. Therefore, the action is made non-final in view of the outstanding issues that must be brought to applicants' attention. The rejection follows below.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 2-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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4. Claim 2 recites the limitation "extract" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite extract. This rejection was made in the office action mailed 8/10/01 and corrected in the response filed 2/08/02 and reintroduced on 2/17/04. Correction is respectfully requested.

Claim Rejections - 35 USC § 102

5. Claims 1-3, 6, 7, 16 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Costanzo (US 6,323,219).

Applicants argue;

a) Costanzo does not disclose applying the composition to mammalian hair, b) does not disclose the method and compositions of applicants invention, c) SLIGRL is not a member of the botanical families set forth in applicants' composition, d) the result of Costanzo's topical application of compositions to the skin would not inevitably be the method of applicants' invention and would not serve to support an inherency rejection and mere application of Costanzo's composition to skin at certain times during the life cycle of a hair would not necessarily inevitable affect changes in a hair that may be located in proximity to the skin being treated if they are applied indiscriminately during the life cycle, e) Costanzo's composition darkens gray hair, and therefore, Costanzo does not disclose methods of claims 1-3, 6, 7, 9, 16 or 19.

Response to Arguments

6. Applicants' arguments filed 1/27/06 have been fully considered but they are not persuasive.

The of the instant method of effecting changes in mammalian hair comprises a method of topical application to the skin of a mammal an effective amount of a topically active composition comprising one or more compounds derived from one or more ... and cucurbitaceae. Thus, for claim 1, applying a composition comprising one or more compounds derived from one or more of the botanical families recited in claim 1 topically to mammalian skin would have the effect accorded to the composition in the claim 1, that is effect changes in mammalian hair appearance and pigmentation, and reducing hair growth and hair follicle and hair shaft size. It is noted that the hair grows on skin.

a) Costanzo topically applies the composition comprising serine protease inhibitor, which may be obtained from Solanaceae, Gramineae, Cucurbitaceae and Leguminosae (column 8, lines 52-67); soybean milk also contains serine protease (column 9, lines 47-53; column 28, lines 50-67). Regarding b), it is noted that Costanzo composition comprising serine protease inhibitor and applies same topically to skin of mammals. Regarding c), SLIGRL is mentioned as one of the components in compositions used to treat skin disorders in one of the embodiments and is noted that the SLIGRL is mentioned as it relates to one of the embodiments and in that embodiment, the composition contains serine protease inhibitor (compound 1 as in formula 1 that inhibits trypsin) and SLIGRL; and it is further noted that the comprising language is open. Regarding d), it is noted that the instant method topically applies composition comprising serine protease inhibitor (at least claims 2 and 3, which limit the compound to the protease inhibitor) to effect the changes in mammalian hair appearance and hair pigmentation. Thus, the topical application of a composition of the prior art that contains serine protease inhibitor inherently would produce the effect of the composition. Therefore, an inherency argument is well

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grounded and flows from topically applying the composition inherently having the accorded effects. Regarding e), it is noted that Costanzo is related to methods and composition for bringing about skin pigmentation and inflammatory disorders (abstract) and in column 10, lines 13-17, Costanzo discloses topically applying the composition to mammalian skin. Claims 1-3 read on the topical method of Costanzo. At least one of the changes in claim 6 is would inherently be met by Costanzo, such as delay in hair growth, reduced follicle and hair shaft size. Only one condition need met by the claim language because one of said changes cannot equal four changes. It is also noted that the claims do not recite and do not support specific times within the hair growth cycle for applying the composition and no specific periods in the cycle is identified for application. The rejection follows.

Costanzo discloses method and composition for “bringing about skin pigmentation and/or for causing skin depigmentation;” the methods and composition of Costanzo can be used as depigmenting compositions, darkening compositions and as compositions for preventing and/or treating immunomediated inflammatory diseases such as asthma and allergic rhinitis (abstract). The composition of Costanzo contains serine protease inhibitors that may be obtained from extracts of Solanaceae, Gramineae, Cucurbitaceae and Leguminosae (column 8, lines 52-67); soybean milk also contains serine protease (column 9, lines 47-53; column 28, lines 50-67).

Costanzo specifically discloses topically applying to mammalian skin pharmaceutical or cosmetic composition in an amount effective to effect changes in pigmentation (column 10, lines 13-17) and soybean milk or other formulations derived directly from legumes is applied to the mammalian skin (column 9, lines 47-52). Costanzo lists gray hair as one of the skin disorders treatable with the composition (column 30, lines 14-27).

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The instant method involves topical application to the skin a topically active composition that comprises one or more compounds derived from one or more of the botanical families. Since the instant method topically applies a composition and Costanzo topically applies to the skin a composition that reads of the instant composition, it would be inherent that the composition of the prior art affects the skin the same way as the instant composition affects the skin. The effect of the composition is inherent. Thus, although Costanzo does not specifically disclose that the composition has an effect on hair growth, since the instant claim 1 and Costanzo apply the same composition to the skin, the effect on the skin from both compositions would be the same.

Claim Rejections - 35 USC § 103

7. Claims 4, 5, 8-14, 16-18, 20-22 and 68-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Costanzo (US 6,323,219) in view of Matsuura et al. (US 6,139,899).

Applicants argue:

a) Costanzo does not disclose or suggest the methods or compositions of applicants' claims explicitly or inherently, b) SLIGRL containing composition is the only suggestion to use composition on hair and topical use of compositions set forth in Costanzo would not have inherently resulted in the methods of applicants' invention, c) claims 69-70 require permeation of the composition into the hair follicle and Costanzo does not disclose permeation of the composition into the hair follicle, d) the combination of Matsuura with Costanzo does not overcome the deficiency of Costanzo not disclosing isoflavones because Matsuura does not describe combination of isoflavones and the compositions set forth in claim 1.

Response to Arguments

8. Applicants' arguments filed 1/27/06 have been fully considered but they are not persuasive.

Regarding a), it is noted that Costanzo discloses topically applying composition containing serine protease inhibitor to the skin and thus inherently discloses applicants' claimed method. Regarding b), it is noted that one of the embodiments in Costanzo contains compound 1, a serine protease inhibitor and SLIGRL and the broad comprising language is open and does not exclude SLIGRL. Regarding c), the method is a topical application process and Costanzo topically applies the composition to the skin and thus the composition would inherently permeate the skin. Regarding d), Matsuura is relied upon for a teaching that soybean milk contains isoflavones and the composition of Costanzo contains soybean milk and would thus contain isoflavones. The rejection follows.

The teaching of Costanzo is discussed above and Costanzo discloses the method of the instant claims, that is, topically applying a composition comprising extracts from the plants Solanaceae, Gramineae, Cucurbitaceae and Leguminosae as discussed above. Regarding claims 4 and 5, there is no showing demonstrating that the amount of the inhibitor provides unusual results. Generally, reciting amounts of serine protease inhibitor will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount is critical. "W[here] the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

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Regarding claims 11-14, 16-18 and 20-22, since the composition of the prior art is applied to the skin, the composition would inherently exhibit the properties of the composition on the skin. Regarding new claims 68-70, it is respectfully noted that the instant method involves application of the composition to the skin to effect inhibition of hair growth, reduction of hair follicle and hair shaft and reduction of hair pigmentation, the prior art applies a composition containing serine protease inhibitor and it would be expected that composition similar to the composition of the instant claims would have the same effect on the skin or hair when topically applied to the skin. Thus, in the alternate, it would be obvious for the same/similar composition to have the same/similar effect on the skin and on the hair.

Regarding claims 8-10, Costanzo does not disclose that the composition comprising the plant extracts contains isoflavones. However, the composition of the prior art Costanzo contains soybean milk extract. But it is known in the prior art, for example, Matsuura, that soybean milk contains isoflavones. Matsuura discloses the presence of isoflavones in soybean milk (abstract; see the whole document). Thus, Matsuura is relied upon for a teaching that soybean milk contains isoflavones. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the composition of Costanzo containing extract of soy bean milk to apply to the skin in order to effect changes in mammalian hair appearance/skin pigmentation/skin depigmentation. One having ordinary skill in the art would have been motivated to apply the composition of Costanzo to the skin with the expectation that the composition containing the extract of soybean milk contains isoflavones that occur naturally in the soybean milk as disclosed by Matsuura and expect the composition to produce changes in the mammalian hair/skin appearance.

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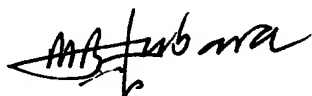
The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

A handwritten signature in black ink, appearing to read "Blessing Fubara", is written over a horizontal line.